U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

SEP 14 2001

Reference No. 01-0228

Richard Tulley, Ph.D.
Director, Clinical Research Laboratory
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, Louisiana 70808-4124

Dear Dr. Tulley:

This is in response to your August 17, 2001 letter requesting clarification on the definition and exceptions in § 173.134 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) for a diagnostic specimen.

A diagnostic specimen is defined in § 173.134(a)(2) as "any human or animal material including, but not limited to, excreta, secreta, blood, blood components, tissue, and tissue fluids, being shipped for purposes of diagnosis."

A diagnostic specimen, even one known to contain an infectious substance, is excepted from the requirements of the HMR unless the material meets the definition of another hazard class. However, please be aware that shipment of a diagnostic specimen that is infectious may be subject to the regulations of other federal agencies with responsibilities for these materials, such as the U.S. Postal Service; the Department of Health and Human Services' Centers for Disease Control and Prevention, and Food and Drug Administration; the Department of Labor's Occupational Safety and Health Administration; or the U.S. Department of Agriculture's Animal Plant and Health Inspection Service. Also, under the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, if a diagnostic specimen is known or suspected of being infectious, it would be classed as a Division 6.2 material. Similarly, RSPA proposed to remove the current exceptions for diagnostic specimens and biological products in a notice of proposed rulemaking published earlier this year (Docket No. RSPA 98-3971 (HM-226), 66 FR 6942, 1/22/01).

I hope this information is helpful.

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

010228

173.134

**Pennington Biomedical Research Center**
LOUISIANA STATE UNIVERSITY

Betts
§173.134(a)(2)
Diagnostic
Specimen
01-0228

August 17, 2001

Edward Mazullo, Director
U.S. Department of Transportation
Research and Special programs Administration
Office of Hazardous Materials Standards
400 7th Street, S.W.
Washington, DC 20590

Dear Mr. Mazullo:

Several people from our institution attended a meeting in New Orleans conducted by the US Department of Transportation on the HAZMAT regulations and said that shipment of human diagnostic specimens would be covered by the regulations requiring training in the proper shipment of specimens. In researching this, I spoke with two people from the HAZMAT Info line (Arthur Pollack and Jeff) who both told me that diagnostic specimens were exempt from the regulations. I would like a clarification to make sure we do the correct thing.

Our center ships human samples (including blood, urine, etc) for testing to several laboratories for the purpose of research at our center and we receive specimens from outside locations for testing at our center. These specimens do not contain any type of infectious agent beyond the things that normal human specimens may contain (possibly hepatitis or HIV-but this information is unknown to us). The purpose may be diagnostic in some cases but is usually for research. What this means is that we may test for certain things such as cholesterol to see if a drug or diet might change those levels in people. The results are usually used in a cross sectional manner, meaning that results are compiled for treatment and control groups and compared statistically. This is very similar to diagnostic specimens, but not exactly the same. What is your opinion on this?

Sincerely,

Richard Tulley

Richard Tulley, Ph.D.
Director, Clinical Research Laboratory

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